

Claims

1 1. A method for transvenously accessing the pericardial space
2 between a heart and its pericardium to perform a medical procedure on the heart,
3 the method comprising the following steps:

4 (a) passing a guide catheter through a selected vein to establish a
5 transvenous route to the right auricle of the heart;

6 (b) passing an infusion guide wire and a leading guide wire through
7 said guide catheter and into the right auricle so that at least one of a distal end of
8 said leading guide wire and a distal end of said infusion guide wire is positioned
9 against a wall of the right auricle, said leading guide wire being located within a
10 lumen of said infusion guide wire;

11 (c) piercing said wall of the right auricle with at least one of said distal
12 end of said leading guide wire and said distal end of said infusion guide wire;

13 (d) advancing at least one of said infusion guide wire and said leading
14 guide wire into the pericardial space; and

15 (e) using said at least one of said infusion guide wire and said leading
16 guide wire to perform a specific medical procedure on the heart.

1 2. The method of claim 1, wherein said step (c) of piercing said wall
2 of the right auricle is performed without attaching a distal end of said guide
3 catheter to said wall of the right auricle.

1 3. The method of claim 2, wherein said leading guide wire has a
2 greater length than said infusion guide wire, and wherein said step (c) of piercing
3 comprises the step of:

4 simultaneously applying an axial force to said infusion guide wire and said
5 leading guide wire until at least one of said distal end of said leading guide wire
6 and said distal end of said infusion guide wire pierces said wall of the right auricle.

1 4. The method of claim 1, wherein step (d) of advancing at least one
2 of said infusion guide wire and said leading guide wire comprises the step of:
3 simultaneously advancing said infusion guide wire and said leading guide
4 wire into the pericardial space.

1 5. The method of claim 4, further comprising the step between steps
2 (d) and (e) of removing said leading guide wire.

1 6. The method of claim 1, wherein step (d) comprises advancing said
2 infusion guide wire into the pericardial space, and wherein the method further
3 comprises the step between steps (d) and (e) of removing said leading guide wire.

1 7. The method of claim 6, wherein said step (e) of using said at least
2 one of said infusion guide wire and said leading guide wire comprises the step of:

3 (e) using said infusion guide wire to deliver a substance to the
4 pericardial space via said lumen of said infusion guide wire, wherein said substance
5 is selected from a group consisting of a medication, a biological agent, a lubricant,
6 a polymer, and a synthetic agent.

1 8. The method of claim 6, wherein said step (e) of using said at least
2 one of said infusion guide wire and said leading guide wire comprises the step of:

3 (e) using said infusion guide wire to perform said specific medical
4 procedure on the heart, said specific medical procedure being selected from the
5 group consisting of

6 (1) withdrawing a fluid from the pericardial space via said
7 lumen of said infusion guide wire,

8 (2) delivering a substance to the pericardial space via said
9 lumen of said infusion guide wire,

10 (3) using a conductor of said infusion guide wire to deliver an
11 electrical signal to the heart from within said pericardial space, and

(4) using a conductor of said infusion guide wire to sense an electrical signal from the heart from within said pericardial space.

9. The method of claim 8, further comprising the steps of:

(f) advancing said leading guide wire back through said infusion guide wire into the pericardial space;

(g) removing said infusion guide wire; and

(h) using said leading guide wire as a conduit over which a desired catheter may be introduced for performing a further specific medical procedure.

10. The method of claim 9, wherein said step (h) comprises the steps of:

using said leading guide wire as a conduit over which a desired catheter may be introduced for performing said further specific medical procedure, said desired catheter and said further specific medical procedure being selected from the group consisting of

(1) passing an electrode catheter over said leading guide wire and into the pericardial space so that a distal end of said electrode catheter is maintained in contact with the epicardium, and using said electrode catheter to deliver electrical energy to said epicardium;

(2) passing an electrode catheter over said leading guide wire and into the pericardial space so that a distal end of said electrode catheter is maintained in contact with the epicardium, and using said electrode catheter to sense electrical energy from said epicardium;

(3) passing a drug delivery catheter over said leading guide wire so that a distal end of said drug delivery catheter is positioned in the

pericardial space, and using said drug delivery catheter to deliver a pharmacologic agent to the pericardial space;

(4) passing a fluid removal catheter over said leading guide wire so that a distal end of said fluid removal catheter is positioned in the pericardial space, and using said fluid removal catheter to remove fluid from the pericardial space; and

(5) passing an imaging catheter over said infusion guide wire so that said imaging catheter is positioned in the pericardial space, and using said imaging catheter to observe at least one of heart muscles, coronary arteries, and the pericardium.

11. The method of claim 1, wherein step (e) comprises the step of using said infusion guide wire as a conduit over which a desired catheter may be introduced for performing said specific medical procedure.

12. The method of claim 11, wherein said step (e) further comprises the steps of:

(e) using said infusion guide wire as a conduit over which a desired catheter may be introduced for performing said specific medical procedure, said desired catheter and said specific medical procedure being selected from the group consisting of

(1) passing an electrode catheter over said infusion guide wire and into the pericardial space so that a distal end of said electrode catheter is maintained in contact with the epicardium, and using said electrode catheter to deliver electrical energy to said epicardium;

(2) passing an electrode catheter over said infusion guide wire and into the pericardial space so that a distal end of said electrode catheter is maintained in contact with the epicardium, and using said electrode catheter to sense electrical energy from said epicardium;

(3) passing a drug delivery catheter over said infusion guide wire so that a distal end of said drug delivery catheter is positioned in the pericardial space, and using said drug delivery catheter to deliver a pharmacologic agent to the pericardial space;

(4) passing a fluid removal catheter over said infusion guide wire so that a distal end of said fluid removal catheter is positioned in the pericardial space, and using said fluid removal catheter to remove fluid from the pericardial space; and

(5) passing an imaging catheter over said infusion guide wire so that said imaging catheter is positioned in the pericardial space, and using said imaging catheter to observe at least one of heart muscles, coronary arteries, and the pericardium.

13. The method of claim 1, further comprising the step between steps (d) and (e) of removing said infusion guide wire.

14. The method of claim 13, wherein said step (e) of using said at least one of said infusion guide wire and said leading guide wire comprises the step of:

(e) using said leading guide wire to perform said specific medical procedure on the heart, said specific medical procedure being selected from the group consisting of

(1) using a conductor of said leading guide wire to deliver an electrical signal to the heart from within said pericardial space, and

(2) using a conductor of said leading guide wire to sense an electrical signal from the heart from within said pericardial space.

15. The method of claim 13, wherein step (e) comprises the step of using said leading guide wire as a conduit over which a desired catheter may be introduced for performing said specific medical procedure.

1 16. The method of claim 15, wherein said step (e) further comprises
2 the steps of:

3 (e) using said leading guide wire as a conduit over which a desired
4 catheter may be introduced for performing said specific medical procedure, said
5 desired catheter and said specific medical procedure being selected from the group
6 consisting of

7 (1) passing an electrode catheter over said leading guide wire
8 and into the pericardial space so that a distal end of said electrode catheter
9 is maintained in contact with the epicardium, and using said electrode
10 catheter to deliver electrical energy to said epicardium;

11 (2) passing an electrode catheter over said leading guide wire
12 and into the pericardial space so that a distal end of said electrode catheter
13 is maintained in contact with the epicardium, and using said electrode
14 catheter to sense electrical energy from said epicardium;

15 (3) passing a drug delivery catheter over said leading guide
16 wire so that a distal end of said drug delivery catheter is positioned in the
17 pericardial space, and using said drug delivery catheter to deliver a
18 pharmacologic agent to the pericardial space;

19 (4) passing a fluid removal catheter over said leading guide
20 wire so that a distal end of said fluid removal catheter is positioned in the
21 pericardial space, and using said fluid removal catheter to remove fluid
22 from the pericardial space; and

23 (5) passing an imaging catheter over said infusion guide wire
24 so that said imaging catheter is positioned in the pericardial space, and
25 using said imaging catheter to observe at least one of heart muscles,
26 coronary arteries, and the pericardium.

1 17. The method of claim 1, wherein said step (a) of passing a guide
2 catheter comprises the steps of:

3 placing an introducer sheath into the selected vein;
4 introducing a guide catheter into said vein through said sheath;
5 guiding said guide catheter downstream through said vein to one of the
6 venae cavae;

7 guiding said guide catheter downstream through said one of the venae
8 cavae to the right atrium, and

9 guiding said guide catheter through the right atrium and into the right
10 auricle.

11 18. The method of claim 17, wherein said step (a) of passing a guide
12 catheter further comprises the step of:

13 advancing said guide catheter into the right auricle so that a distal end of
14 said guide catheter is placed against the wall of the right auricle; and

15 using one of fluoroscopic imaging and echocardiographic imaging to
16 visually follow the progress of said guide catheter into the right auricle; and

17 confirming proper placement of said guide catheter against the wall of the
18 right auricle when said distal end of said guide catheter moves with the beating of
19 the heart.

20 19. The method of claim 18, wherein said step (c) of piercing
21 comprises the step of:

22 waiting, once said distal end of said leading guide wire is positioned
23 against said wall of the right auricle, for movement of the heart from its rhythmic
24 beating to cause said distal end of said leading guide wire to pierce said wall of the
25 right auricle.
26

1 20. The method of claim 1, wherein said step (d) of advancing at least
2 one of said infusion guide wire and said leading guide wire into the pericardial
3 space further comprises the steps of:

4 using one of fluoroscopic imaging and echocardiographic imaging to
5 visually follow the progress of said at least one of said infusion guide wire and said
6 leading guide wire into the pericardial space; and

7 confirming proper placement of said at least one of said infusion guide wire
8 and said leading guide wire in the pericardial space when said at least one of said
9 infusion guide wire and said leading guide wire begins to take the shape of the
10 contour of the heart.

21. The method of claim 20, wherein said step (d) of advancing said
infusion guide wire further comprises the step of:

 simultaneously advancing said leading guide wire and said infusion guide
wire into the pericardial space.

22. The method of claim 21, wherein said step (d) of simultaneously
advancing said leading guide wire and said infusion guide wire further comprises
the steps of:

 using one of fluoroscopic imaging and echocardiographic imaging to
visually follow the progress of said leading guide wire and said infusion guide wire
into the pericardial space; and

 confirming proper placement of said leading guide wire and said infusion
guide wire in the pericardial space when said leading guide wire and said infusion
guide wire begin to take the shape of the contour of the heart.

23. A method for transvenously removing fluid from the pericardial
space between a heart and its pericardium to treat cardiac tamponade, the method
comprising the following steps:

4 (a) passing a guide catheter through a vein to establish a transvenous
5 route to the right auricle of the heart;

6 (b) simultaneously passing an infusion guide wire and an leading guide
7 wire through said guide catheter and into the right auricle so that a distal end of
8 said leading guide wire is positioned against a wall of the right auricle, said leading
9 guide wire being located within a lumen of said infusion guide wire;

10 (c) piercing said wall of the right auricle with said distal end of said
11 leading guide wire;

12 (d) advancing said infusion guide wire into the pericardial space; and

13 (e) removing the fluid from the pericardial space.

24. The method of claim 23, wherein said step (c) of piercing said wall
of the right auricle is performed without attaching a distal end of said guide
catheter to said wall of the right auricle.

25. The method of claim 23, wherein step (e) of removing fluid
comprises the steps of:

removing said leading guide wire; and

using said infusion guide wire to remove the fluid from the pericardial
space, the fluid being removed through said lumen in said infusion guide wire.

26. The method of claim 23, wherein said leading guide wire has a
greater length than said infusion guide wire, and wherein said step (c) of piercing
comprises the step of:

simultaneously applying an axial force said infusion guide wire and said
leading guide wire until said distal end of said leading guide wire pierces said wall
of the right auricle.

1 27. A method for transvenously accessing the pericardial space
2 between a heart and its pericardium to perform a medical procedure on the heart,
3 the method comprising the following steps:

4 (a) passing a guide catheter through a selected vein to establish a
5 transvenous route to the right auricle of the heart;

6 (b) passing a leading guide wire through said guide catheter and into
7 the right auricle so that a distal end of said leading guide wire is positioned against
8 a wall of the right auricle;

9 (c) piercing said wall of the right auricle with said distal end of said
10 leading guide wire;

11 (d) advancing said leading guide wire into the pericardial space; and

12 (e) using said leading guide wire to perform a specific medical
13 procedure on the heart.

1 28. The method of claim 27, wherein said step (c) of piercing said wall
2 of the right auricle is performed without attaching a distal end of said guide
3 catheter to said wall of the right auricle.

1 29. The method of claim 28, wherein said step (c) of piercing
2 comprises the step of:

3 applying an axial force to a proximal end of said leading guide wire until
4 said distal end of said leading guide wire pierces said wall of the right auricle.

5 30. A kit for transvenously accessing the pericardial space between a
6 heart and its pericardium to perform a medical procedure on the heart, the kit
7 comprising:

8 an infusion guide wire; and

9 a leading guide wire having a diameter sufficiently small to be passed
10 through a lumen of said infusion guide wire, said leading guide wire having a
11 sufficient length to pass through and protrude from a distal end of said infusion

8 guide wire, and having a distal end capable of penetrating a wall of the right
9 atrium of the subject's heart,

10 wherein said infusion guide wire and said leading guide wire both have
11 sufficient flexibility to permit said infusion guide wire and said leading guide wire
12 to be simultaneously passed through said guide catheter into the right atrium of
13 the subject's heart via a transvenous route.

31. The kit of claim 30, wherein said infusion wire has a diameter
sufficiently small to be passed through a lumen of said guide catheter, said infusion
guide wire having a sufficient length to be passed through said guide catheter into
the right atrium of the subject's heart via a transvenous route.

32. The kit of claim 30, further comprising:
a guide catheter having sufficient length and flexibility to be inserted into
the right atrium of a subject's heart via a transvenous route.

33. The kit of claim 30, wherein said infusion guide wire has sufficient
flexibility to permit said infusion guide wire to conform at least partially to the
contour of the heart when said infusion guide wire is extended outward from a
distal end of said guide catheter and into the pericardial space.

34. The kit of claim 33, further comprising:
an aspiration catheter having a lumen of sufficient diameter so that said
aspiration catheter may be passed over said infusion guide wire and into the
pericardial space for the removal of fluid from the pericardial space to treat
cardiac tamponade.

35. The kit of claim 30, wherein said leading guide wire has sufficient
flexibility to permit said leading guide wire to conform at least partially to the

3
C4
contour of the heart when said leading guide wire is extended outward from a distal end of said guide catheter and into the pericardial space.

1
G2
B332
5
36. The kit of claim 35, further comprising:
an aspiration catheter having a lumen of sufficient diameter so that said aspiration catheter may be passed over said leading guide wire and into the pericardial space for the removal of fluid from the pericardial space to treat cardiac tamponade.

1
2
09759439-012601
37. The kit of claim 30, wherein said guide wire has a diameter between 0.010 inches and 0.018 inches.

38. The kit of claim 36, wherein said guide wire has a diameter of 0.014 inches.

1
2
3
39. The kit of claim 30, wherein said distal end of said leading guide wire protrudes approximately 2mm from said distal end of said infusion guide wire.

1
G2
B332
4
40. A kit for transvenously accessing the pericardial space between a heart and its pericardium to perform a medical procedure on the heart, the kit comprising:

5
a guide catheter having sufficient length and flexibility to be inserted into the right atrium of a subject's heart via a transvenous route;

6
7
a leading guide wire having a diameter sufficiently small to be passed through a lumen of said guide catheter,

8
9
10
wherein said leading guide wire has sufficient length to pass through and protrude from a distal end of said guide catheter, a distal end capable of penetrating a wall of the right atrium of the subject's heart, and sufficient flexibility

11

to permit said leading guide wire to be passed through said guide catheter and into the right atrium of the subject's heart via a transvenous route.

1

41. The kit of claim 40, wherein said leading guide wire has sufficient flexibility to permit said leading guide wire to conform at least partially to the contour of the heart when said leading guide wire is extended outward from a distal end of said guide catheter and into the pericardial space.

4

09270" 6E469260

A17D

B57